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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,018	05/31/2001	Stephen William Watson Michnick	ODDY 002	8430

7590 07/14/2004

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EXAMINER
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FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/14

**Office Action Summary**

Application No.

09/870,018

Applicant(s)

MICHNICK ET AL.

Examiner

Jeffrey Fredman

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 43-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 43-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status***

1. Claims 1-17 and 43-62 are pending.

Claims 1-17 and 43-62 are rejected.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

***Claim Rejections - 35 USC § 112***

2. The rejection of claims 1-14, 6-7, 43-46, 48-53, 54-62 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment to the claims.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-17 and 43-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Balint et al (US 2004/0038317).

Balint teaches an assay method of claims 1, 8, 12, 43, 56, comprising (see abstract).

(A) generating:

1) at least a first fragment of a reporter molecule linked to a first interacting domain and at least a second fragment of a reporter molecule linked to a second interacting domain, (see page 20, paragraph 113, where the  $\omega$  fragment of  $\beta$ -lactamase is linked to Her-2/neu and the  $\alpha$  fragment of  $\beta$ -lactamase is linked to a protein which interacts with Her-2/neu) or 2) nucleic acid molecules that code for A) 1) and subsequently allowing said nucleic acid molecules to produce their coded products (see page 21, paragraph 0116 which shows nucleic acid encoding protein chimeras); then, (B) allowing interaction of said domains (see page 20, paragraph 0113, and page 21, paragraph 0115); and (C) detecting reconstituted reporter molecule activity (see page 20, paragraph 0113 and page 21, paragraph 0115), where said reporter molecule catalyzes the hydrolysis of the amide bond of  $\beta$ -lactam rings in a penicillin- or cephalosporin-compound (see page 21, paragraph 0115, where nitrocefin, a cephalosporinase substrate is used and is cleaved by  $\beta$ -lactamase which cleaves the  $\beta$ -lactam ring).

With regard to claims 2-3, 44-45, Balint teaches the use of the enzyme,  $\beta$ -lactamase (see entire specification, including page 20, paragraph 113).

With regard to claim 4, 46, Balint teaches hydrolyzing the  $\beta$ -lactam ring, which is irreversible (see page 21, paragraph 0115).

With regard to claims 5, 11, 47, 54, Balint teaches the use of Nitrocefin as a substrate (see page 21, paragraph 0115).

With regard to claim 6, 48, Balint teaches an in vivo assay (see example 9).

With regard to claim 7, 49, Balint teaches the use of  $\beta$ -lactamase (see example 9), which is not normally present in eukaryotes.

With regard to claim 9, 50-52, Balint demonstrates a signal to noise ratio of more than 30 (see paragraph 0091, which discusses signal to noise ratios over 100).

With regard to claim 10, 12, 53, 55, Balint teaches a signal, color change of cleaved nitrocefin, which can be observed by eye (and whose signal is entrapped in the cells) (see page 21, paragraph 0115).

With regard to claims 13-14, 57-59, Balint teaches the use of fluorescent signals (see paragraph 0113, where fluorogenic  $\beta$ -lactamase substrates are taught).

With regard to claim 15, 60, 62, Balint teaches screening for compounds that inhibit binding (see abstract).

With regard to claims 16-17, 61, Balint teaches that selection can be based upon survival and growth (see example 3, paragraph 0079, where selection was based upon growth and survival of cells plated onto ampicillin).

With regard to claims 43-62, Balint teaches two molecules linked together (see entire specification, including examples 3 and 9).

### ***Response to Arguments***

5. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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Applicant's amendment to the claims has overcome the Cornish reference for the reasons given in Applicant's response. However, a new rejection, necessitated by the amendment, relying upon the Balint reference is now made.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

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